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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/014,488      | 12/14/2001  | Paul Clayton         | 02481.1769          | 1028             |

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10/22/2002

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EXAMINER

KIM, JENNIFER M

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 10/22/2002

5

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/014,488

Applicant(s)

CLAYTON, PAUL

Examiner

Jennifer Kim

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 14 December 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### **Claims 1-33 are presented for examination.**

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kosbab (WO 98/33494) of record in view of Gilles et al.(U.S.Patent No. 6,248,375B1).

Kosbab on the abstract, page 2, lines 10-35, page 3, lines 25-30, page 4, line 23-page18, page 47-51 teaches a composition comprising active agents and their dosage amounts set forth in claims 1,6,11,13,17,22 and 29 for nutrient and therapeutic composition use for disease conditions associated with diabetes.

Kosbab on page 4, lines 5-20 teaches that the nutrient composition can be combined with components that regulate glucose or insulin level and the use of functionally similar components which are structurally distinct or derived from different sources allows the inclusion of sufficiently high levels of total material to achieve a desired level of activity while avoiding the potential toxic effect that may result from use of high levels of any single component.

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Gilles et al. on the abstract, column 10, lines 52-69, column 22, claim 11 and 12, column 10, lines 20-25, teach a nutritional composition for treatment of diabetes comprising FOS and other vitamins and minerals set forth in Applicant's claims 1,6,11,13,17,22 and 29.

Gilles et al. on column 10, lines 20-50 teach that FOS is readily available and it is preferential energy source to beneficial bacteria but against potential pathogens in the nutritional composition.

The difference between primary reference and Applicant's claimed invention is absence of FOS and insulin. However, one of ordinary skill in the art would be motivated to employ FOS and insulin in view of Gilles et al. since Gilles et al. teach that FOS in diabetic composition is preferential energy source to beneficial bacteria in the diabetic nutritional composition. Furthermore, Kosbab taught that any of the components that regulate glucose or insulin level can be combined with Kosbab's composition. Therefore, the skilled artisan would be motivated to combine well known insulin (component that regulates glucose or insulin level, column 1, lines 22-25, Gilles et al.) and any other active agents taught by Gilles's composition including FOS to Kosbab's composition with reasonable expectation of success in formulating a diabetic nutritional formulation since the use of functionally similar components which are structurally distinct or derived from different sources allows the inclusion of sufficiently high levels of total material to achieve a desired level of activity while avoiding the potential toxic effect that may result from use of high levels of any single component.

One would have been motivated to combine these references and make such modification because they are drawn to same technical fields (constituted with same active ingredient and well

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known vitamins and minerals routinely incorporated in diabetic nutritional supplement) and pertinent to the problem which applicant concerns about. MPEP 2141.01(a).

The amounts of active agents to be used, the pharmaceutical forms, e.g., tablets, etc; mode of administration, flavors, surfactant, and process of making are all deemed obvious since they are all within the knowledge of the skilled pharmacologist and the broad range of usual amounts are taught by Kosbab and represent conventional formulations and modes of administration.

For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 103.

None of the claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 703-308-2232. The examiner can normally be reached on Monday through Friday 8:30am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 703-305-1877. The fax phone numbers


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for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



Theodore J. Criares  
Primary Examiner  
Art Unit 1617

jmk  
October 16, 2002